

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

JUDITH ELAINE BYERS, PATRICIA A.
CLIFTON, and JOHN C. CLIFTON on behalf
of themselves and all others similarly situated,

Plaintiffs,

NO. 2:12-cv-02812

vs.

JOHNSON & JOHNSON, INC.; JOHNSON &
JOHNSON SERVICES, INC.; JOHNSON &
JOHNSON INTERNATIONAL; ETHICON,
INC.; ETHICON WOMEN'S HEALTH AND
UROLOGY, and GYNECARE,

JURY TRIAL DEMANDED

Defendants.

**ANSWER AND DEFENSES OF DEFENDANT ETHICON, INC. TO
PLAINTIFFS' CLASS ACTION COMPLAINT**

Defendant Ethicon, Inc. ("Ethicon"), by and through its attorneys, responds to
Plaintiffs' Class Action Complaint ("Complaint") as follows.

RESPONSE TO "INTRODUCTION"

1. Ethicon admits only that Plaintiffs purport to bring an action for damages
allegedly sustained by Plaintiffs. Ethicon denies the remaining allegations and legal
conclusions contained in Paragraph 1 of Plaintiffs' Complaint.

2. Ethicon lacks sufficient knowledge or information so as to form a belief
as to the truth of the allegations contained in Paragraph 2 of Plaintiffs' Complaint and,
therefore, denies those allegations.

RESPONSE TO "JURISDICTION"

3. Paragraph 3 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 4 of Plaintiffs' Complaint and, therefore, denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. Ethicon admits only that it has tested, developed, manufactured, labeled, marketed, distributed, promoted and sold certain pelvic mesh products for uses consistent with their packaging and labeling and that its products have been available for purchase in Tennessee. Ethicon denies that Johnson & Johnson has tested, developed, manufactured, labeled, distributed, promoted or sold any product. Ethicon denies the remaining allegations contained in Paragraph 5 of Plaintiffs' Complaint.

6. Ethicon denies the allegations contained in Paragraph 6 of Plaintiffs' Complaint.

RESPONSE TO "THE PARTIES"

7. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first and second sentences of Paragraph 7 of Plaintiffs' Complaint and, therefore, denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint.

8. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first and second sentences of

Paragraph 8 of Plaintiffs' Complaint and, therefore, denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 8 of Plaintiffs' Complaint.

9. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first and second sentences of Paragraph 9 of Plaintiffs' Complaint and, therefore, denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 9 of Plaintiffs' Complaint.

10. Ethicon admits only that Johnson & Johnson Services, Inc. is a New Jersey corporation with its principal place of business in New Jersey. Ethicon denies the remaining allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Ethicon admits only that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey. Johnson & Johnson does not manufacture, market, distribute or sell any product. Ethicon denies the remaining allegations contained in Paragraph 11 of Plaintiffs' Complaint.

12. Ethicon admits only that Johnson & Johnson International is a New Jersey corporation with its principal place of business in New Jersey. Ethicon denies the remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint as phrased.

13. Ethicon admits only that it is a New Jersey corporation with its principal place of business in New Jersey. Ethicon denies the remaining allegations contained in Paragraph 13 of Plaintiffs' Complaint as phrased.

14. Ethicon admits only that Ethicon Women's Health & Urology is a division of Ethicon, Inc. and denies the remaining allegations contained in Paragraph 14 of Plaintiffs' Complaint.

15. Ethicon denies the allegations contained in Paragraph 15 of Plaintiffs' Complaint as phrased.

16. Ethicon admits only that it marketed and sold certain pelvic mesh products for uses consistent with their packaging and labeling and that its products have been available for purchase in Tennessee. Ethicon denies that Johnson & Johnson has marketed or sold any product. Ethicon denies the remaining allegations contained in Paragraph 16 of Plaintiffs' Complaint.

RESPONSE TO "FACTUAL ALLEGATIONS"

17. Ethicon admits only that it has marketed and sold Gynemesh for uses consistent with its packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. Ethicon admits only that it has marketed and sold Prolene Mesh for uses consistent with its packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Ethicon admits only that it has marketed and sold Prolift, Prolift Anterior, Prolift Posterior and Prolift Total for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 19 of Plaintiffs' Complaint.

20. Ethicon admits only that it has marketed and sold Prolift +M for uses consistent with its packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 20 of Plaintiffs' Complaint.

21. Ethicon admits only that it has marketed and sold TVT, TVT-O and TVT-S for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 21 of Plaintiffs' Complaint.

22. Ethicon admits that it has developed, designed, licensed, manufactured, distributed, sold, marketed, advertised and sold Prolene Mesh, Gynemesh, Prolift, Prolift +M and TVT for uses consistent with their packaging and labeling and that its products have been available for purchase in Tennessee. Ethicon denies the remaining allegations contained in Paragraph 22 of Plaintiffs' Complaint.

23. Ethicon admits that it has designed, patented, manufactured, labeled, marketed, sold and distributed certain "pelvic repair products" for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 23 of Plaintiffs' Complaint.

24. Ethicon admits that it has designed, manufactured, marketed, packaged, labeled and sold certain "pelvic repair products" for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Ethicon admits only that it has marketed and sold certain "pelvic repair products" for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 25 of Plaintiffs' Complaint.

26. Paragraph 26 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 26 of Plaintiffs' Complaint.

27. Ethicon admits that its “pelvic repair products” are safe and effective for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 27 of Plaintiffs’ Complaint.

28. Ethicon admits that it has marketed and sold certain “pelvic repair products” for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 28 of Plaintiffs’ Complaint.

29. Ethicon denies the allegations contained in Paragraph 29 of Plaintiffs’ Complaint.

30. Ethicon denies the allegations contained in Paragraph 30 of Plaintiffs’ Complaint.

31. Ethicon denies the allegations contained in Paragraph 31, including subparts (a) – (h), of Plaintiffs’ Complaint.

32. Ethicon denies the allegations contained in Paragraph 32 of Plaintiffs’ Complaint.

33. Ethicon denies the allegations contained in Paragraph 33 of Plaintiffs’ Complaint.

34. Ethicon states that the Public Health Notification referenced in Paragraph 34 of Plaintiffs’ Complaint speaks for itself and denies the remaining allegations contained in Paragraph 34 of Plaintiffs’ Complaint.

35. Ethicon states that the Safety Communication referenced in Paragraph 35 of Plaintiffs' Complaint speaks for itself and denies the remaining allegations contained in Paragraph 35 of Plaintiffs' Complaint.

36. Paragraph 36 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

37. Ethicon denies the allegations contained in Paragraph 37, including subparts (a) – (d), of Plaintiffs' Complaint.

38. Ethicon denies the allegations contained in Paragraph 38 of Plaintiffs' Complaint.

39. Ethicon denies the allegations contained in Paragraph 39 of Plaintiffs' Complaint.

40. Ethicon denies the allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Ethicon denies the allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 42 of Plaintiffs' Complaint and, therefore, denies those allegations.

43. Ethicon denies the allegations contained in Paragraph 43 of Plaintiffs' Complaint.

44. Ethicon lacks sufficient knowledge or information to know whether any of the Plaintiffs used any of its products, and Ethicon denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 45 of Plaintiffs' Complaint and, therefore, denies those allegations.

46. Ethicon states that the medical and scientific literature referenced in Paragraph 46 of Plaintiffs' Complaint speaks for itself. Ethicon denies the remaining allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. Ethicon denies the allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Ethicon denies the allegations contained in Paragraph 48 of Plaintiffs' Complaint.

49. Ethicon admits that it has certain duties imposed on it and denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Ethicon denies the allegations contained in Paragraph 50, including subparts (a) – (g), of Plaintiffs' Complaint.

51. Ethicon states that the studies and medical literature referenced in Paragraph 51 of Plaintiffs' Complaint speak for themselves. Ethicon denies the remaining allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Ethicon denies the allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Ethicon denies the allegations contained in Paragraph 53 of Plaintiffs' Complaint.

54. Ethicon denies the allegations contained in Paragraph 54 of Plaintiffs' Complaint.

55. Ethicon denies the allegations contained in Paragraph 55 of Plaintiffs' Complaint.

56. Ethicon denies the allegations contained in Paragraph 56 of Plaintiffs' Complaint.

57. Ethicon denies the allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. Paragraph 58 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent that a response is required, Ethicon admits that it has certain duties imposed on it by law and denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 58 of Plaintiffs' Complaint.

59. Ethicon denies the allegations contained in Paragraph 59 of Plaintiffs' Complaint.

60. Ethicon denies the allegations contained in Paragraph 60 of Plaintiffs' Complaint.

61. Ethicon denies the allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Ethicon denies the allegations contained in Paragraph 62 of Plaintiffs' Complaint.

63. Ethicon denies the allegations contained in Paragraph 63 of Plaintiffs' Complaint.

64. Ethicon denies the allegations contained in Paragraph 64 of Plaintiffs' Complaint.

65. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 65 of Plaintiffs' Complaint and, therefore, denies those allegations.

66. Ethicon denies the allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Ethicon denies the allegations contained in Paragraph 67 of Plaintiffs' Complaint.

68. Ethicon denies the allegations contained in Paragraph 68 of Plaintiffs' Complaint.

69. Ethicon states the studies and medical literature referenced in Paragraph 69 of Plaintiffs' Complaint speak for themselves. Ethicon denies the remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Paragraph 70 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. Ethicon denies the allegations contained in Paragraph 71 of Plaintiffs' Complaint.

RESPONSE TO "CLASS ALLEGATIONS"

72. Paragraph 72 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

73. Paragraph 73, including all subparts, of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

74. Paragraph 74 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

75. Paragraph 75 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

76. Paragraph 76 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

77. Paragraph 77 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

78. Paragraph 78, including all subparts, of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

79. Paragraph 79 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Paragraph 80 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 80 of Plaintiffs' Complaint.

RESPONSE TO "CAUSES OF ACTION"

RESPONSE TO "COUNT I"

81. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-80 of Plaintiffs' Complaint.

82. Ethicon admits that it has certain duties imposed on it by law and denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 82 of Plaintiffs' Complaint.

83. Ethicon denies the allegations contained in Paragraph 83 of Plaintiffs' Complaint.

84. Ethicon denies the allegations contained in Paragraph 84 of Plaintiffs' Complaint.

85. Ethicon denies the allegations contained in Paragraph 85 of Plaintiffs' Complaint.

RESPONSE TO "COUNT II"

86. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-85 of Plaintiffs' Complaint.

87. Ethicon denies the allegations contained in Paragraph 87 of Plaintiffs' Complaint.

88. Ethicon denies the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Ethicon denies the allegations contained in Paragraph 89 of Plaintiffs' Complaint.

90. Ethicon denies the allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Ethicon denies the allegations contained in Paragraph 91 of Plaintiffs' Complaint.

RESPONSE TO "COUNT III"

92. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-91 of Plaintiffs' Complaint.

93. Ethicon denies the allegations contained in Paragraph 93 of Plaintiffs' Complaint.

94. Ethicon denies the allegations contained in Paragraph 94 of Plaintiffs' Complaint.

95. Ethicon denies the allegations contained in Paragraph 95 of Plaintiffs' Complaint.

RESPONSE TO "COUNT IV"

96. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-95 of Plaintiffs' Complaint.

97. Ethicon denies the allegations contained in Paragraph 97 of Plaintiffs' Complaint.

98. Ethicon denies the allegations contained in Paragraph 98 of Plaintiffs' Complaint.

99. Ethicon denies the allegations contained in Paragraph 99 of Plaintiffs' Complaint.

100. Ethicon denies the allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Ethicon denies the allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Ethicon denies the allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-102 of Plaintiffs' Complaint.

104. Ethicon denies the allegations contained in Paragraph 104 of Plaintiffs' Complaint.

105. Ethicon denies the allegations contained in Paragraph 105 of Plaintiffs' Complaint.

106. Ethicon denies the allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. Ethicon denies the allegations contained in Paragraph 107 of Plaintiffs' Complaint.

RESPONSE TO "COUNT V"

108. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-107 of Plaintiffs' Complaint.

109. Ethicon denies the allegations contained in Paragraph 109, including subparts (a) – (i), of Plaintiffs' Complaint.

110. Ethicon denies the allegations contained in Paragraph 110 of Plaintiffs' Complaint.

111. Ethicon denies the allegations contained in Paragraph 111 of Plaintiffs' Complaint.

RESPONSE TO "COUNT VI"

112. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-111 of Plaintiffs' Complaint.

113. Ethicon admits that its "pelvic repair products" are safe and reasonably fit for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 113 of Plaintiffs' Complaint.

114. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 114 of Plaintiffs' Complaint and, therefore, denies those allegations.

115. Ethicon lacks sufficient knowledge or information to know what Plaintiffs or Plaintiffs' physicians relied on, and Ethicon denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 115 of Plaintiffs' Complaint.

116. Ethicon denies the allegations contained in Paragraph 116 of Plaintiffs' Complaint.

117. Ethicon denies the allegations contained in Paragraph 117 of Plaintiffs' Complaint.

118. Ethicon denies the allegations contained in Paragraph 118 of Plaintiffs' Complaint.

RESPONSE TO "COUNT VII"

119. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-118 of Plaintiffs' Complaint.

120. Ethicon admits that its "pelvic repair products" are merchantable and fit for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 121 of Plaintiffs' Complaint and, therefore, denies those allegations.

122. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 122 of Plaintiffs' Complaint and, therefore, denies those allegations.

123. Ethicon denies the allegations contained in Paragraph 123 of Plaintiffs' Complaint.

124. Ethicon denies the allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. Ethicon denies the allegations contained in Paragraph 125 of Plaintiffs' Complaint.

RESPONSE TO "COUNT VIII"

126. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-125 of Plaintiffs' Complaint.

127. Ethicon denies the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Ethicon denies the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Ethicon denies the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Ethicon denies the allegations contained in Paragraph 130, including subparts (a) – (k), of Plaintiffs' Complaint.

131. Ethicon admits that it has certain duties imposed on it by law and denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. Ethicon denies the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Ethicon denies the allegations contained in Paragraph 133 of Plaintiffs' Complaint.

134. Ethicon denies the allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Ethicon denies the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Ethicon denies the allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Ethicon lacks sufficient knowledge or information to know what Plaintiffs relied on, and Ethicon denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Ethicon denies the allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Ethicon admits that it has certain duties imposed on it by law and denies that it breached any duty. Ethicon denies the remaining allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. Ethicon denies the allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Ethicon denies the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Ethicon denies the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Ethicon denies the allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Ethicon denies the allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. Ethicon states that any submissions it has made to the FDA speak for themselves, and Ethicon denies the remaining allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. Ethicon denies the allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Ethicon denies the allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Ethicon denies the allegations contained in Paragraph 148 of Plaintiffs' Complaint.

149. Ethicon denies the allegations contained in Paragraph 149 of Plaintiffs' Complaint.

150. Ethicon denies the allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Ethicon denies the allegations contained in Paragraph 151 of Plaintiffs' Complaint.

152. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 152 of Plaintiffs' Complaint and, therefore, denies those allegations.

153. Ethicon denies the allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. Ethicon denies the allegations contained in Paragraph 154 of Plaintiffs' Complaint.

RESPONSE TO "COUNT IX"

155. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-154 of Plaintiffs' Complaint.

156. Ethicon denies the allegations contained in Paragraph 156 of Plaintiffs' Complaint.

157. Ethicon denies the allegations contained in Paragraph 157 of Plaintiffs' Complaint.

158. Ethicon states that the publication referenced in Paragraph 158 of Plaintiffs' Complaint speaks for itself. Ethicon denies the remaining allegations contained in Paragraph 158 of Plaintiffs' Complaint.

159. Ethicon denies the allegations contained in Paragraph 159 of Plaintiffs' Complaint.

160. Ethicon denies the allegations contained in Paragraph 160 of Plaintiffs' Complaint.

161. Ethicon denies the allegations contained in Paragraph 161 of Plaintiffs' Complaint.

162. Ethicon denies the allegations contained in Paragraph 162 of Plaintiffs' Complaint.

RESPONSE TO "COUNT X"

163. Ethicon denies the allegations contained in Paragraph 163 of Plaintiffs' Complaint.

164. Ethicon denies the allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. Ethicon denies the allegations contained in Paragraph 165 of Plaintiffs' Complaint.

166. Ethicon denies the allegations contained in Paragraph 166 of Plaintiffs' Complaint.

167. Ethicon denies the allegations contained in Paragraph 167 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XI"

168. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-167 of Plaintiffs' Complaint.

169. Ethicon admits that it has manufactured and sold certain "pelvic repair products" for uses consistent with their packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 169 of Plaintiffs' Complaint.

170. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 170 of Plaintiffs' Complaint and, therefore, denies those allegations.

171. Ethicon denies the allegations contained in Paragraph 171 of Plaintiffs' Complaint.

172. Ethicon denies the allegations contained in Paragraph 172 of Plaintiffs' Complaint.

173. Ethicon denies the allegations contained in Paragraph 173 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XII"

174. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-173 of Plaintiffs' Complaint.

175. Ethicon denies the allegations contained in Paragraph 175 of Plaintiffs' Complaint.

176. Ethicon lacks sufficient knowledge or information to know what Plaintiffs relied on, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 176 of Plaintiffs' Complaint.

177. Paragraph 177 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 177 of Plaintiffs' Complaint.

178. Ethicon denies the allegations contained in Paragraph 178 of Plaintiffs' Complaint.

179. Ethicon denies the allegations contained in Paragraph 179 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XIII"

180. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-179 of Plaintiffs' Complaint.

181. Ethicon denies the allegations contained in Paragraph 181 of Plaintiffs' Complaint.

182. Ethicon denies the allegations contained in Paragraph 182 of Plaintiffs' Complaint.

183. Paragraph 183 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 183 of Plaintiffs' Complaint.

184. Ethicon denies the allegations contained in Paragraph 184 of Plaintiffs' Complaint.

185. Ethicon denies the allegations contained in Paragraph 185, including all subparts, of Plaintiffs' Complaint.

RESPONSE TO "COUNT XIV"

186. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-185 of Plaintiffs' Complaint.

187. Paragraph 187 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

188. Paragraph 188 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

189. Paragraph 189 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 189 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XV"

190. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-189 of Plaintiffs' Complaint.

191. Ethicon denies the allegations contained in Paragraph 191 of Plaintiffs' Complaint.

192. Ethicon denies the allegations contained in Paragraph 192 of Plaintiffs' Complaint.

193. Ethicon denies the allegations contained in Paragraph 193 of Plaintiffs' Complaint.

194. Ethicon denies the allegations contained in Paragraph 194 of Plaintiffs' Complaint.

195. Ethicon denies the allegations contained in Paragraph 195 of Plaintiffs' Complaint.

196. Ethicon denies the allegations contained in Paragraph 196 of Plaintiffs' Complaint.

197. Ethicon denies the allegations contained in Paragraph 197 of Plaintiffs' Complaint.

198. Ethicon denies the allegations contained in Paragraph 198 of Plaintiffs' Complaint.

199. Ethicon denies the allegations contained in Paragraph 199 of Plaintiffs' Complaint.

200. Ethicon denies the allegations contained in Paragraph 200 of Plaintiffs' Complaint.

201. Ethicon denies the allegations contained in Paragraph 201 of Plaintiffs' Complaint.

202. Ethicon denies the allegations contained in Paragraph 202 of Plaintiffs' Complaint.

203. Ethicon denies the allegations contained in Paragraph 203 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XVI"

204. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-203 of Plaintiffs' Complaint.

205. Paragraph 205 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 205 of Plaintiffs' Complaint.

206. Paragraph 206 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 206 of Plaintiffs' Complaint.

207. Paragraph 207 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

208. Ethicon denies the allegations contained in Paragraph 208 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XVII"

209. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-208 of Plaintiffs' Complaint.

210. Paragraph 210 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

211. Paragraph 211 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

212. Paragraph 212 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent that a response is required, Ethicon denies the allegations contained in Paragraph 212 of Plaintiffs' Complaint.

213. Ethicon denies the allegations contained in Paragraph 213 of Plaintiffs' Complaint.

214. Paragraph 214 of Plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon.

RESPONSE TO "COUNT XVIII"

215. Ethicon incorporates by reference its responses to each and every allegation contained in Paragraphs 1-214 of Plaintiffs' Complaint.

216. Ethicon denies the allegations contained in Paragraph 216 of Plaintiffs' Complaint.

217. Ethicon denies the allegations contained in Paragraph 217 of Plaintiffs' Complaint.

218. Ethicon denies the allegations contained in Paragraph 218, including subparts (a) – (n), of Plaintiffs' Complaint.

219. Ethicon denies the allegations contained in Paragraph 219 of Plaintiffs' Complaint.

RESPONSE TO "COUNT XIX"

220. Ethicon incorporates its responses to each and every allegation contained in Paragraphs 1-219 of Plaintiffs' Complaint.

221. Ethicon denies the allegations contained in Paragraph 221 of Plaintiffs' Complaint.

222. Ethicon denies the allegations contained in Paragraph 222 of Plaintiffs' Complaint.

223. Ethicon denies the allegations contained in Paragraph 223 of Plaintiffs' Complaint.

RESPONSE TO "JURY TRIAL DEMAND"

224. Ethicon demands a jury trial.

RESPONSE TO "PRAYER FOR RELIEF"

In response to the unnumbered “Prayer,” Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief whatsoever, including subparts (A) – (J), from Ethicon.

SEPARATE DEFENSES

FIRST DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted.

SECOND DEFENSE

Certain of plaintiffs’ claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

THIRD DEFENSE

Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in Tennessee and/or any other state whose law is deemed to apply in this case.

FOURTH DEFENSE

Ethicon specifically pleads as to plaintiffs’ fraud, fraud by concealment and negligent misrepresentation claims, all affirmative defenses available to Ethicon under the rules and statutes of Tennessee and/or any state whose law is deemed to apply in this case, and under any common law principles of Tennessee and/or any state whose law is deemed to apply in this case.

FIFTH DEFENSE

Plaintiffs’ claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device

Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the products at issue are regulated by the U.S. Food and Drug Administration (“FDA”) under the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations.

SIXTH DEFENSE

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and plaintiffs’ claims are accordingly barred.

SEVENTH DEFENSE

Plaintiffs’ claims against Ethicon are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. § 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

EIGHTH DEFENSE

Plaintiffs’ claims are barred because Ethicon complied with all applicable state and federal statutes regarding the products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that plaintiffs’ claims are not barred, Ethicon is entitled to a presumption that the products at issue are free from any defect or defective

condition as the plans or design for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were adopted.

NINTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and regulations promulgated there under.

TENTH DEFENSE

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.

ELEVENTH DEFENSE

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to petition the government.

TWELFTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law

with determining the content of warnings and labeling for medical devices.

THIRTEENTH DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulation of FDA.

FOURTEENTH DEFENSE

Plaintiffs' claim for punitive damages is barred because the products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the products at issue.

FIFTEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for any of the products at issue.

SIXTEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

SEVENTEENTH DEFENSE

Ethicon made no express or implied representations or warranties of any kind to plaintiffs, nor did plaintiffs rely on any representations or warranties made by Ethicon to others. To the extent plaintiffs relied upon any representations or

warranties, such reliance was unjustified.

EIGHTEENTH DEFENSE

Any express or implied warranties alleged to have been made by Ethicon were disclaimed.

NINETEENTH DEFENSE

Ethicon did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Ethicon, and/or by plaintiffs' failure to give Ethicon timely notice of the alleged breach of warranty and an opportunity to cure. Ethicon further specifically pleads as to any breach of warranty claim all affirmative defenses available to Ethicon under the Uniform Commercial Code, as enacted in Tennessee and/or any state whose law is deemed to apply in this case, and under the common law principles of Tennessee and/or any state whose law is deemed to apply in this case.

TWENTIETH DEFENSE

Ethicon specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Ethicon under the rules and statutes of Tennessee and/or any state whose law is deemed to apply in this case, and under the common law principles of Tennessee and/or any state whose law is deemed to apply in this case.

TWENTY-FIRST DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon given the state of scientific knowledge and

state-of-the-art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of FDA.

TWENTY-SECOND DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that plaintiffs seek to recover herein.

TWENTY-THIRD DEFENSE

Plaintiffs’ claims are barred, in whole or in part, because Ethicon acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its products.

TWENTY-FOURTH DEFENSE

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

TWENTY-FIFTH DEFENSE

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

TWENTY-SIXTH DEFENSE

Plaintiffs’ claims are barred in whole or in part because the products at issue were consistent with and/or exceeded consumer expectations.

TWENTY-SEVENTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

TWENTY-EIGHTH DEFENSE

Adequate and complete warnings and instructions were provided with the products at issue. The products at issue were neither defective nor unreasonably dangerous when used according to its Instructions for Use.

TWENTY-NINTH DEFENSE

At all relevant times, the warnings and instructions accompanying the products at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

THIRTIETH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

THIRTY-FIRST DEFENSE

Ethicon is not liable to plaintiffs because the end users of the products at issue, plaintiffs' physician(s), were sophisticated users of the products.

THIRTY-SECOND DEFENSE

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way

liable. Plaintiffs are not, therefore, entitled to recover from Ethicon in this action. As to plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of Tennessee and/or the applicable states.

THIRTY-THIRD DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Ethicon's liability, if any, for plaintiffs' alleged damages.

THIRTY-FOURTH DEFENSE

The plaintiffs voluntarily and unreasonably chose to encounter known dangers.

THIRTY-FIFTH DEFENSE

The liability of Ethicon, if any, for plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of Tennessee and/or the applicable states.

THIRTY-SIXTH DEFENSE

In the event Ethicon is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any

applicable contribution or apportionment statute, law or policy of Tennessee and/or the applicable states.

THIRTY-SEVENTH DEFENSE

There is no causal relationship between Ethicon's conduct and the injuries and damages alleged by plaintiffs in the Complaint.

THIRTY-EIGHTH DEFENSE

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bars in whole or in part the damages which plaintiffs seek to recover herein.

THIRTY-NINTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

FORTIETH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FORTY-FIRST DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the products at issue in this case, if any, were caused by the acts or omissions of third parties for

which Ethicon has no legal responsibility.

FORTY-SECOND DEFENSE

Ethicon expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FORTY-THIRD DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

FORTY-FOURTH DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

FORTY-FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

FORTY-SIXTH DEFENSE

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to preserve evidence necessary to the

determination of the claim.

FORTY-SEVENTH DEFENSE

Plaintiffs' claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than plaintiff, or, if not disclosed by plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

FORTY-EIGHTH DEFENSE

Some or all of plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of Tennessee and/or the applicable states.

FORTY-NINTH DEFENSE

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

FIFTIETH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by plaintiffs' failure to mitigate such damages.

FIFTY-FIRST DEFENSE

The sale, labeling and marketing of the products at issue in this litigation

is not, and was not, likely to mislead or deceive the public.

FIFTY-SECOND DEFENSE

The products at issue were altered after the products left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability.

FIFTY-THIRD DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

FIFTY-FOURTH DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comment j and k of the Restatement (Second) of Torts.

FIFTY-FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

FIFTY-SIXTH DEFENSE

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

FIFTY-SEVENTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

FIFTY-EIGHTH DEFENSE

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

FIFTY-NINTH DEFENSE

No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SIXTIETH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the applicable states.

SIXTY-FIRST DEFENSE

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited

from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the State where each plaintiff resides, or in any other way subjecting Ethicon to impermissible multiple punishment for the same alleged wrong.

SIXTY-SECOND DEFENSE

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process clause of the Fourteenth Amendment to the United States Constitution.

SIXTY-THIRD DEFENSE

With respect to plaintiffs' demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of*

North America, Inc. v. Gore, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

SIXTY-FOURTH DEFENSE

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

SIXTY-FIFTH DEFENSE

Ethicon specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SIXTY-SIXTH DEFENSE

Ethicon specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SIXTY-SEVENTH DEFENSE

Ethicon specifically pleads as to plaintiffs' negligence claims all affirmative defenses available to Ethicon under the rules and statutes of any state whose

law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SIXTY-EIGHTH DEFENSE

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

SIXTY-NINTH DEFENSE

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

WHEREFORE, Defendant Ethicon, Inc. prays that:

- (1) Plaintiffs take nothing by reason of the Complaint;
- (2) the Complaint be dismissed in its entirety and that a Judgment against Plaintiffs and in favor of Ethicon, Inc. be entered;
- (3) Ethicon, Inc. be awarded its costs and expenses; and
- (4) this Court award Ethicon Inc. any other and general or specific relief as this Court may deem just and proper.

THIS, the 19th day of September, 2012.

Respectfully submitted,

/s/ Kari L. Sutherland
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CERTIFICATE OF SERVICE

I hereby certify that I have filed the foregoing with the Clerk of Court by using the CM/ECF system on September 19, 2012. I also certify that a true and correct copy of the same was sent via U.S. mail, postage pre-paid, on September 19, 2012, to the following counsel of record:

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